

WHAT IS CLAIMED IS:

Sub B1

1. A method for treating a mammal having non-invasive fungus-induced intestinal mucositis, comprising mucoadministering to the digestive tract of said mammal a formulation in an amount, at a frequency, and for a duration effective to reduce or eliminate said non-invasive fungus-induced intestinal mucositis, said formulation comprising an antifungal agent.

2. The method of claim 1, wherein said mammal is a human.

3. The method of claim 1, wherein said mammal is nonatopic.

4. The method of claim 1, wherein said mammal is immunocompetent.

10 5. The method of claim 1, wherein said non-invasive fungus-induced intestinal mucositis is characterized by polyp formation or polypoid change.

6. The method of claim 1, wherein said non-invasive fungus-induced intestinal mucositis is chronic.

Sub B2

15 7. The method of claim 1, wherein said formulation is in a solid, liquid, or aerosol form.

8. The method of claim 1, wherein said formulation is in a form selected from the group consisting of a powder, crystalline substance, gel, paste, ointment, salve, cream, solution, suspension, partial liquid, spray, nebulae, mist, atomized vapor, aerosol, and tincture.

20 9. The method of claim 1, wherein said formulation is in the form of a capsule.

9
10. The method of claim 8, wherein said capsule is a regulated release capsule.

10
11. The method of claim 10, wherein said regulated release capsule is a pH regulated release capsule.

11
5 12. The method of claim 10, wherein said regulated release capsule is a time regulated release capsule.

12
13. The method of claim 1, wherein said mucoadministration is a direct mucoadministration.

14. ~~The method of claim 13, wherein said direct mucoadministration comprises orally applying said formulation to said digestive tract.~~

10 15. ~~The method of claim 13, wherein said direct mucoadministration comprises applying said formulation to said digestive tract by way of an enema.~~

13
16. The method of claim 1, wherein said antifungal agent comprises a macrolide.

14
15 17. The method of claim 1, wherein said antifungal agent comprises an azole.

15
18. The method of claim 1, wherein said antifungal agent interpolates fungal cell wall components.

16
19.
20. The method of claim 1, wherein said antifungal agent comprises a sterol inhibitor.

The method of claim 1, wherein said antifungal agent comprises an antifungal agent selected from the group consisting of amphotericin B, ketoconazole, itraconazole, saperconazole, voriconazole, flucytosine, miconazole, fluconazole, griseofulvin, clotrimazole, econazole, terconazole, butoconazole, 5 oxiconazole, sulconazole, ciclopirox olamine, halopropgin, tolnaftate, naftifine, terbinafine hydrochloride, morpholines, nystatin, natamycin, butenafine, undecylenic acid, Whitefield's ointment, propionic acid, and caprylic acid.

21. The method of claim 20, wherein said antifungal agent comprises an antifungal agent selected from the group consisting of amphotericin B, 10 ketoconazole, itraconazole, saperconazole, and voriconazole.

22. The method of claim 20, wherein said antifungal agent comprises amphotericin B.

23. The method of claim 20, wherein said antifungal agent comprises itraconazole.

15 24. The method of claim 1, wherein said formulation comprises about 0.01 ng to about 1000 mg of said antifungal agent.

25. The method of claim 1, wherein said formulation comprises about 1 ng to about 500 mg of said antifungal agent.

26. The method of claim 1, wherein said formulation comprises about 100 20 mg of said antifungal agent.

27. The method of claim 1, wherein said formulation comprises a plurality of antifungal agents.

28. The method of claim 1, wherein said effective amount of said formulation comprises about 0.01 ng to about 1000 mg of said antifungal agent per kg of body weight of said mammal.

29. The method of claim 1, wherein said effective amount of said formulation comprises about 1 ng to about 500 mg of said antifungal agent per kg of body weight of said mammal.

30. The method of claim 1, wherein said effective amount of said formulation remains constant during said effective duration.

31. The method of claim 1, wherein said effective frequency of said mucoadministration is from about four times a day to about once every other week.

32. The method of claim 1, wherein said effective frequency of said mucoadministration is from about twice a day to about once a week.

33. The method of claim 1, wherein said effective frequency of said mucoadministration is more frequent than once a day.

34. The method of claim 1, wherein said effective frequency of said mucoadministration is more frequent than once a week.

35. The method of claim 1, wherein said effective duration is greater than about 7 days.

36. The method of claim 1, wherein said effective duration is greater than about 14 days.

RECEIVED
U.S. PATENT AND TRADEMARK OFFICE
APR 22 1980

37. The method of claim 1, wherein said effective duration is greater than about 30 days.

38. The method of claim 1, wherein said effective duration is greater than about 60 days.

5 39. The method of claim 1, wherein said effective duration is greater than about 90 days.

40. The method of claim 1, wherein said formulation comprises a compound selected from the group consisting of pharmaceutically acceptable aqueous vehicles, pharmaceutically acceptable solid vehicles, mucolytic agents, antibacterial agents, 10 anti-inflammatory agents, immunosuppressants, dilators, vaso-constrictors, steroids, and therapeutic compounds.

10 41. The method of claim 1, wherein said method comprises administering to said mammal a second formulation.

42. The method of claim 41, wherein said second formulation comprises a 15 compound selected from the group consisting of antifungal agents, pharmaceutically acceptable aqueous vehicles, pharmaceutically acceptable solid vehicles, mucolytic agents, antibacterial agents, anti-inflammatory agents, immunosuppressants, dilators, vaso-constrictors, steroids, and therapeutic compounds.

20 43. The method of claim 1, said method comprising, after said mucoadministration, prophylactically mucoadministering to said mammal a prophylactic formulation in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis, said prophylactic formulation comprising an antifungal agent.

SEARCHED INDEXED
SERIALIZED FILED
APR 22 1976
FBI - NEW YORK

44. The method of claim 43, wherein said prophylactic mucoadministration comprises direct mucoadministration.

45. A method for prophylactically treating a mammal at risk for developing non-invasive fungus-induced intestinal mucositis, comprising mucoadministering to
5 said mammal a formulation in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis, said formulation comprising an antifungal agent.

46. A method for treating a mammal having a non-invasive fungus-induced intestinal mucositis, comprising the steps of:
10 a) identifying said mammal, and
b) mucoadministering to at least a portion of the digestive tract of said mammal a formulation in an amount, at a frequency, and for a duration effective to reduce or eliminate said non-invasive fungus-induced intestinal mucositis, said formulation comprising an antifungal agent.

15 47. The method of claim 46, wherein said identifying comprises diagnosing.

48. A method for prophylactically treating a mammal at risk for developing non-invasive fungus-induced intestinal mucositis, comprising the steps of:
20 a) identifying said mammal, and
b) mucoadministering to at least a portion of the digestive tract of said mammal a formulation in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis, said formulation comprising an antifungal agent.

25 49. An article of manufacture, comprising packaging material and a formulation contained within said packaging material, wherein said formulation comprises an antifungal agent and wherein said packaging material comprises a

label or package insert indicating that said formulation can be mucoadministered to a mammal having non-invasive fungus-induced intestinal mucositis in an amount, at a frequency, and for a duration effective to reduce or eliminate said non-invasive fungus-induced intestinal mucositis.

5 50. An article of manufacture, comprising packaging material and a formulation contained within said packaging material, wherein said formulation comprises an antifungal agent and wherein said packaging material comprises a label or package insert indicating that said formulation can be mucoadministered to a mammal at risk for developing non-invasive fungus-induced intestinal mucositis

10 in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis.

Adel
B37